

Docket No.: 085742-0010

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Benjamin OSHLACK

Patent Number: 7,514,100

Application No.: 10/660,349

Filed: September 11, 2003

For: CONTROLLED RELEASE HYDROCODONE FORMULATIONS

PETITION UNDER 37 CFR 1.182

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under 37 CFR 1.182, a petition may be submitted to the Director to decide situations not specifically provided for in the patent regulations. This Petition Under 37 CFR 1.182 requests reconsideration of the patent term adjustment calculation for U.S. Patent No. 7,514,100, filed as Application No. 10/660,349 on September 11, 2003 and issued on April 7, 2009. This patent falls into a category of patents entitled to additional patent term adjustment (PTA) with no regulation to provide for the granting of such PTA. This petition is accompanied by the \$400 fee set forth in 37 CFR 1.17(f).

The U.S. Patent & Trademark Office ("PTO") permits a Request for Recalculation of Patent Term Adjustment in View of Wyeth (PTO/SB/131) for patents issued before March 2, 2010 that were not issued more than 180 days before the Request was filed. The instant patent does not fall within this time period restriction. Thus,

Applicant respectfully requests that the Director decide to have the PTO recalculate the patent term adjustment (“PTA”) for this patent.

The arbitrary date restrictions for PTA recalculation of patents falling victim to the PTO’s old, pre-*Wyeth* calculation deprives patents falling outside of the date requirements for filing a Form PTO/SB/131 of a means to obtain the valuable patent term adjustment due them. PTA under 35 U.S.C. § 154 is in effect for applications filed after May 29, 2000. The instant patent was filed after this date. It should not be deprived of PTA calculated according to a proper interpretation of the statute because no regulation provides for recapture of PTA lost through the PTO’s old, incorrect method of calculation.

Summary of Patent Term Adjustment under 35 U.S.C. § 154

35 U.S.C. § 154 guarantees that the PTO will provide at least one notification under section 132 or a notice of allowance not later than 14 months after the date on which the application was filed, and subsequent notifications within four months of an applicant’s response. PTO delays beyond these times are referred to as “A” delays.

35 U.S.C. § 154 further guarantees a no more than 3-year application pendency. This does not include time consumed by continued examination requested by the applicant. PTO delays beyond this 3-year period are referred to as “B” delays. PTO delays do not include “overlap” under 35 U.S.C. § 154(b)(2)(A). Applicant delay is deducted from the PTO delay to arrive at the PTA.

PTO Practice Prior to *Wyeth*

Prior to the Federal Circuit's holding in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the PTO interpreted "no overlap" under 35 U.S.C. § 154 to mean that any A delay would necessarily result in B delay. Thus, an applicant was entitled to a PTA equal to the greater of the two types of delay, but not both.

The Correct Calculation under *Wyeth*

In *Wyeth*, the Federal Circuit stated that: "[n]o overlap happens unless the violations occur at the same time." *Id.* at 1369-70. According to *Wyeth*, an applicant can be entitled to both A and B delays because no B delay occurs before the 3-year pendancy date. Thus, there can be no overlap for A delays occurring before the 3-year pendancy date.

The PTO's Old Calculation Deprived the Applicant of 336 Days of PTA

The PTO calculated 668 days of PTA for the instant '100 patent. As illustrated below, the correct calculation under *Wyeth* is 1004 days. A copy of the prosecution history, downloaded from the PTO's PAIR database is attached as Exhibit A.

(a) A Delays

(i) Applicant filed a Response after Non-Final Action on January 14, 2005. The PTO mailed an *Ex Parte Quayle* Action on May 31, 2005. The PTO Action was 17 days beyond 4-months from the May 31, 2005 Response, resulting in a 17 day A delay.

(ii) Applicant filed a Response after *Ex Parte Quayle* Action on June 27, 2005. The PTO's next Office Action was mailed on October 4, 2007. This Action was 707 days beyond 4 months from the June 27, 2005 Response, resulting in a 707 day A delay.

(b) B Delay

The '349 application was filed on September 11, 2003. A Request for Continued Examination (RCE) was filed on September 15, 2008. This resulted in a B delay of 735 days as follows. Three years from September 11, 2003 is September 11, 2006. The interval between September 11, 2006 and the September 15, 2008 RCE filing date is 735 days.

(c) Overlap

The overlap is the period of A delay extending beyond the 3-year pendency date into the B delay period. Here, this is the period from September 6, 2006 to October 4, 2007 and is an overlap of 388 days.

(d) Non-overlapped PTO Delay

The non-overlap delay is $17 + 707 + 735 - 388 = 1,071$ days.

(e) Applicant Delays

(i) Applicant delay was 61 days for the period in excess of three months for the Response filed March 5, 2008 following the October 4, 2007 Non-Final Rejection;

(ii) Applicant delayed 3 days for the period in excess of three months from the RCE filed September 15, 2008 following the June 12, 2008 Final Rejection, and

(iii) Applicant delayed 3 days for the period in excess of three months for the Issue Fee payment received February 20, 2009 following the November 17, 2008 Notice of Allowance.

(iv) The total applicant delay was $61 + 3 + 3 = 67$ days.

PTA under *Wyeth*

The correct PTA is $1,071 - 67 = 1,004$ days.

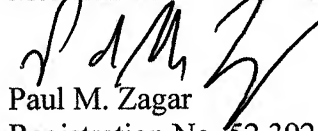
Conclusion

As detailed above, the '100 patent should have been granted 1,004 days of PTA. The PTO, using the old, incorrect calculation method, granted 668 days of PTA. Thus, the applicant was deprived of 336 days of patent term adjustment through no fault of its own. The PTO has provided a means for patents issued before March 2, 2010 to have a recalculation of their PTA via a Request for Recalculation of Patent Term Adjustment in View of *Wyeth* (PTO/SB/131) as long as the patent was not issued more than 180 days before the Request was filed. No regulation provides for a recalculation of the PTA for patents falling under 35 U.S.C. § 154 but outside of the PTO's arbitrary date restrictions. Applicant requests that the Director decide that a recalculation of the PTA in the instant case be performed and that the PTO recognize the additional PTA due this patent.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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EXHIBIT A

Transaction History



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10/660,349

CONTROLLED RELEASE HYDROCODONE FORMULATIONS

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Transaction History

| Date | Transaction Description |
|------------|--|
| 04-07-2009 | Recordation of Patent Grant Mailed |
| 03-18-2009 | Issue Notification Mailed |
| 04-07-2009 | Patent Issue Date Used in PTA Calculation |
| 02-26-2009 | Dispatch to FDC |
| 02-25-2009 | Application Is Considered Ready for Issue |
| 02-20-2009 | Issue Fee Payment Verified |
| 02-20-2009 | Issue Fee Payment Received |
| 11-17-2008 | Mail Examiner's Amendment |
| 11-17-2008 | Mail Notice of Allowance |
| 11-14-2008 | Document Verification |
| 11-14-2008 | Notice of Allowance Data Verification Completed |
| 11-10-2008 | Examiner's Amendment Communication |
| 09-22-2008 | Information Disclosure Statement considered |
| 09-22-2008 | Reference capture on IDS |
| 09-22-2008 | Information Disclosure Statement (IDS) Filed |
| 10-22-2008 | Date Forwarded to Examiner |
| 10-22-2008 | Date Forwarded to Examiner |
| 09-15-2008 | Request for Continued Examination (RCE) |
| 10-22-2008 | Disposal for a RCE / CPA / R129 |
| 10-04-2008 | Case Docketed to Examiner in GAU |
| 09-22-2008 | Information Disclosure Statement (IDS) Filed |
| 09-15-2008 | Workflow - Request for RCE - Begin |
| 06-12-2008 | Mail Final Rejection (PTOL - 326) |
| 06-09-2008 | Final Rejection |
| 11-13-2007 | Information Disclosure Statement considered |
| 04-05-2008 | Date Forwarded to Examiner |
| 03-05-2008 | Response after Non-Final Action |
| 03-05-2008 | Request for Extension of Time - Granted |
| 01-08-2008 | Case Docketed to Examiner in GAU |
| 11-13-2007 | Reference capture on IDS |
| 11-13-2007 | Information Disclosure Statement (IDS) Filed |
| 11-13-2007 | Information Disclosure Statement (IDS) Filed |
| 10-04-2007 | Mail Non-Final Rejection |
| 10-01-2007 | Non-Final Rejection |
| 01-14-2005 | Information Disclosure Statement considered |
| 09-11-2003 | Information Disclosure Statement considered |
| 04-19-2007 | Case Docketed to Examiner in GAU |
| 06-27-2005 | Oath or Declaration Filed (Including Supplemental) |
| 04-17-2007 | Date Forwarded to Examiner |
| 06-27-2005 | Response after Ex Parte Quayle Action |
| 05-02-2006 | Case Docketed to Examiner in GAU |
| 08-28-2005 | Case Docketed to Examiner in GAU |
| 05-31-2005 | Mail Ex Parte Quayle Action (PTOL - 326) |
| 05-26-2005 | Ex Parte Quayle Action |
| 05-18-2005 | Case Docketed to Examiner in GAU |
| 05-17-2005 | Paralegal TD Not accepted |
| 09-11-2003 | Preliminary Amendment |
| 04-05-2005 | Case Docketed to Examiner in GAU |
| 01-14-2005 | Information Disclosure Statement (IDS) Filed |
| 01-14-2005 | Information Disclosure Statement (IDS) Filed |

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|------------|---|
| 02-11-2005 | Date Forwarded to Examiner |
| 01-14-2005 | Response after Non-Final Action |
| 01-14-2005 | Workflow incoming amendment IFW |
| 10-15-2004 | Mail Non-Final Rejection |
| 10-01-2004 | Non-Final Rejection |
| 07-08-2004 | Case Docketed to Examiner in GAU |
| 07-08-2004 | IFW TSS Processing by Tech Center Complete |
| 09-11-2003 | Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received |
| 09-11-2003 | Reference capture on IDS |
| 09-11-2003 | Information Disclosure Statement (IDS) Filed |
| 09-11-2003 | Information Disclosure Statement (IDS) Filed |
| 12-05-2003 | Application Is Now Complete |
| 12-04-2003 | Application Return from OIPE |
| 12-05-2003 | Application Is Now Complete |
| 12-04-2003 | Application Return TO OIPE |
| 12-04-2003 | Application Dispatched from OIPE |
| 12-04-2003 | Application Is Now Complete |
| 11-24-2003 | Cleared by OIPE CSR |
| 10-20-2003 | IFW Scan & PACR Auto Security Review |
| 09-11-2003 | Initial Exam Team nn |

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